IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:25-cv-00104

ELI LILLY AND COMPANY,

Plaintiff,

v.

THRIVE HEALTH AND WELLNESS, LLC,
D/B/A THRIVE HEALTH SOLUTIONS,
THRIVE HEALTH, AND THRIVE COLORADO,

Defendant.

COMPLAINT FOR FALSE ADVERTISING AND DECEPTIVE TRADE PRACTICES

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1. Defendant Thrive Health and Wellness, LLC, d/b/a Thrive Health Solutions, Thrive Health, and Thrive Colorado ("Thrive") has designed its website and advertising materials to falsely communicate to consumers that Thrive's untested and unapproved compounded drug—sold as "MEGALean – Premium Tirzepatide Injections" ("MEGALean")—is clinically tested to facilitate weight loss and improve blood sugar, and "100% Pure." But there is nothing "pure" about Thrive's products. When Lilly tested them, they were contaminated with potentially *deadly* bacteria. In reality, Thrive's MEGALean products are unstudied, unapproved, and potentially dangerous drugs being falsely promoted as safe, effective, and clinically studied for adults with type 2 diabetes or obesity. Plaintiff Eli Lilly and Company ("Lilly") therefore brings this action to protect the public from Thrive's dangerous, deceptive, and unlawful practices and products.

2. Thrive's claims that its offers "pure Tirzepatide products"[1] are false. Thrive has no basis to make those claims, since Thrive's MEGALean products have not been tested for safety, quality, or efficacy in clinical trials. And testing has proven that it is not true. Testing of a sample of Thrive's MEGALean (Tirzepatide) Injections "Level 1" revealed the presence of *Micrococcus luteus* (*M. Luteus*) contamination, with the sample developing bacterial growth in a sterile environment. *M. Luteus* is a kind of catalase-, oxidase-, and Gram-positive cocci found in natural environments such as soil and water resources. *M. Luteus* can cause fatal infections and has been reported to possibly cause infections such as hepatic and brain abscesses, native valve endocarditis, bacteremia, and septic arthritis in immunosuppressive patients.[2]

3. Thrive's false and deceptive marketing of its MEGALean products poses a direct patient-safety risk. Thrive's promotional materials and public statements have the tendency to deceive the public as to the inherent nature of its MEGALean products, and improperly lure individuals away from safe and effective FDA-approved medications. Further, Thrive's advertising contains no notice of the risks associated with its MEGALean products and deceives consumers as to their safety and efficacy. Lilly therefore brings this false advertising action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq*. and Colorado's Deceptive Trade Practices Act, C.R.S. §§ 6-1-101 *et seq*.

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[1] https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406.

[2] *See* https://pmc.ncbi.nlm.nih.gov/articles/PMC8459002/.

THE PARTIES

4. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana and has its principal place of business in Indiana.

5. Defendant Thrive is a Colorado limited liability company with a principal place of business at 88 Inverness Cir. E, Unit A204, Englewood, CO 80112 in this District.

6. Thrive also conducts business through its website "https://thrivecolorado.com." Thrive's website allows users to book appointments for weight loss treatments at a location in Englewood, Colorado[3] and to purchase Thrive's MEGALean products for shipment.[4]

JURISDICTION AND VENUE

7. The Court has subject matter jurisdiction over the Lanham Act cause of action pleaded in this case pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331. The Court has supplemental jurisdiction over the state law cause of action pleaded herein pursuant to 28 U.S.C. § 1367(a).

8. Thrive is subject to personal jurisdiction in this District because Thrive is incorporated in this State and operates and conducts business in this District, including by unlawfully promoting its MEGALean products. Additionally, Thrive's principal place of business is in this District.

9. Venue is proper in this District and division pursuant to 28 U.S.C. § 1391 because Thrive operates and conducts business in this District.

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[3] https://www.myaestheticspro.com/BN/index.cfm?05E56F092F85DDA6D438573D5E053919 [https://perma.cc/S6XX-S8V3].

[4] https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406.

FACTUAL ALLEGATIONS

I. LILLY'S FDA-APPROVED TIRZEPATIDE INJECTABLE MEDICINES

A. Lilly's Long History of Developing and Manufacturing Safe and Effective Medicines

10. Lilly is an international medicine company and pharmaceutical manufacturer. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries. Today, Lilly's medicines help tens of millions of patients across the globe, including in Colorado.

11. Lilly manufactures its medicines under strict controls in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that Lilly's medicines meet its rigorous quality and safety standards. Transforming active pharmaceutical ingredients, or API, into medicine is a complex, methodical, and science-based process. Lilly follows Current Good Manufacturing Practices ("CGMP") across the design, monitoring, and control of manufacturing processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from chemical synthesis of the API to formulation, device assembly, and packaging—requires extensive testing and controls and specialized equipment.

12. Lilly is also subject to—and encourages—FDA oversight and compliance obligations, including routine FDA inspections, adverse event reporting obligations, and post-market surveillance and studies. Additionally, Lilly's medicines must be, and always are, accompanied by important labels, instructions, and warnings, which themselves are approved by FDA.

B. MOUNJARO® AND ZEPBOUND®

13. Using its experience and expertise, Lilly developed MOUNJARO® and ZEPBOUND®, which were approved by FDA for sale to the public in 2022 and 2023, respectively. Today, Lilly manufactures, markets, and sells MOUNJARO® and ZEPBOUND® throughout Colorado and the United States, among other geographies.

14. Both MOUNJARO® and ZEPBOUND® contain tirzepatide as their API, which targets both GIP and GLP-1 hormone receptors.

15. Specifically, MOUNJARO® is designed to improve glycemic control in adults with type 2 diabetes mellitus (in addition to diet and exercise). As FDA has noted, "[d]espite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals."[5] MOUNJARO® targets this problem. When used as directed, MOUNJARO® has been clinically proven to improve blood sugar control more effectively than other diabetes therapies.

16. ZEPBOUND® is designed to help the millions of American adults with obesity or who are overweight and have weight-related medical problems. As FDA has noted, ZEPBOUND® "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and maintenance)" through a new method of hormone receptor activation.[6] Accordingly, FDA has indicated ZEPBOUND® to reduce excess body weight and maintain

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[5] https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement).

[6] https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition, and to treat moderate to severe obstructive sleep apnea in adults with obesity.

17. Lilly exclusively owns the intellectual property rights related to MOUNJARO® and ZEPBOUND® and is the only lawful supplier of those medicines.

C. The FDA Approval Process

18. FDA approved MOUNJARO® and ZEPBOUND® pursuant to Lilly's marketing application, itself the culmination of a lengthy clinical trial process designed to develop, study, and bring safe medicines to patients so that—in FDA's words—"American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."[7] Over the course of nearly a decade, Lilly completed thirty-seven pre-clinical studies and clinical trials for these medicines.

19. MOUNJARO® and ZEPBOUND® are the only FDA-approved medicines containing tirzepatide in the United States.

II. DRUG COMPOUNDING AND ITS INHERENT RISKS

20. Compounding is a "practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist,

[7] https://www.fda.gov/drugs/development-approval-process-drugs (FDA explainer of new drug development process).

combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[8]

21. For example, if an individual patient is allergic to an ingredient in an FDA-approved medicine, a compounding pharmacy could produce a version of that medication that does not contain the allergen.

22. As FDA itself makes clear, "[c]ompounded drugs are not FDA-approved."[9] This means FDA does not review compounded drugs to evaluate their safety, effectiveness, or quality before they reach patients. Specifically, unlike FDA-approved medications, many compounded drugs do not require clinical testing and are not reviewed and approved by FDA for safety and efficacy. Further, many compounders are not subject to labeling requirements, need not comply with Good Manufacturing Practice regulations, their facilities are not subject to inspections by regulatory authorities, and they have no reporting requirements for adverse events.

23. For that reason, FDA has warned that "[c]ompounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs . . . exposes patients to potentially serious health risks."[10] Indeed, FDA recently reiterated that compounded drugs that purport to contain tirzepatide "have not undergone

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[8] https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (FDA guidance on drug compounding law compliance).

[9] https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

[10] https://web.archive.org/web/20240803214713/https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (June 29, 2022 FDA drug compounding FAQ).

FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process."[11] Moreover, compounded drugs prepared at state-licensed pharmacies "are not subject to CGMP requirements and are subject to less robust production standards that provide less assurance of quality."[12]

24. For instance, on November 1, 2024, FDA issued a warning about drugs compounded by Fullerton Wellness LLC of California after a patient noticed a black particulate in a vial of Fullerton's compounded semaglutide, and a joint FDA-California investigation uncovered conditions at Fullerton that could cause its drugs, including tirzepatide, to become contaminated.[13]

25. Health risks from compounded drugs are serious. In 2021, a compounding pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue.[14] At least 68 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months, even though patients suffered near-immediate adverse events, including permanent blindness.[15] One patient had believed "every pill

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[11] https://www.fda.gov/media/184606/download (Declaratory Order: Resolution of Shortages of Tirzepatide Injection Products at 10).

[12] *Id.*

[13] https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

[14] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries (FDA press announcement re guilty plea).

[15] https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (WFAA article re outbreak).

you take, every shot you take is tested" and was surprised to learn that compounded drugs were neither fully tested nor deemed safe or otherwise approved by FDA.[16]

26. Lilly has seen problems firsthand for compounded tirzepatide. Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. For instance, Lilly has discovered through testing that compounded drugs advertised as tirzepatide contain high impurity levels, low potency levels, different colors (pink, instead of colorless), or a chemical structure different from the tirzepatide in Lilly's FDA-approved medicines. Indeed, testing conducted on a sample of Thrive's tirzepatide offering (*i.e.*, MEGALean) revealed the presence of *Micrococcus luteus* contamination, a bacteria that can lead to fatal blood infections and that has been "reported to possibly cause infections such as hepatic and brain abscess, native valve endocarditis, bacteremia, and septic arthritis in immunosuppressive patients."[17]

27. Consequences from compounded drugs may be deadly. In October 2012, compounded drugs contaminated with a fungus were shipped throughout the country and later injected into patients' spines and joints. After these contaminated products were injected into nearly 14,000 patients, more than 60 people died of fungal meningitis.[18] Afterwards, FDA commented:

> The 2012 fungal meningitis outbreak was not an isolated event. It was the most serious in a long history of serious adverse events associated with contaminated, super-potent, mislabeled, or otherwise poor quality compounded drugs. In addition, many serious adverse events linked to poor quality compounded drugs, including outbreaks of infections and deaths have occurred since then. And,

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16 *Id.*

17 https://pmc.ncbi.nlm.nih.gov/articles/PMC8459002/.

18 *Id.*

> because most compounders do not report adverse events to FDA, the agency may not be aware of adverse events associated with compounded drugs unless a health care provider submits an adverse event report regarding his or her patients or a state official notifies FDA.[19]

Company executives were convicted and received sentences of up to 14 years in prison.[20]

28. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths.[21] There are also instances of close calls, particularly for sterile injectables. For example, in 2022 FDA inspected 503A pharmacy North American Customer Laboratories, LLC d/b/a FarmaKeio Superior Custom Compounding and found that it "routinely use[d] non-pharmaceutical grade components for compounding drug products" and "[n]on-sterilized equipment . . . in sterile drug production,"[22] and issued a warning letter—that appears to be unresolved—for "serious deficiencies in . . . practices for producing drug products intended or expected to be sterile, which put patients at risk."[23] As a result of these findings, FDA also

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19 https://www.fda.gov/media/102493/download (FDA Compounding Progress Report).

20 https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison. (DOJ press release on compounder prison sentence).

21 *Id.*

22 https://www.fda.gov/media/160771/download (Form FDA 483 to N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding (Mar. 10, 2022)).

23 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-american-custom-laboratories-llc-dba-farmakeio-superior-custom-compounding-642792-11182022 (Warning Letter from Div. of Pharma. Quality Op. II to J. Graves, Vice President, N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding (Nov. 18, 2022)).

recommended a voluntary recall of all of FarmaKeio's unexpired drug products that are intended to be sterile.[24]

29. These risks have extended to compounded tirzepatide.

30. Given the popularity of Lilly's MOUNJARO® and ZEPBOUND® medicines, numerous businesses, including Thrive, have begun to manufacture and/or market unapproved compounded products purportedly featuring tirzepatide.

31. As this conduct has become more prevalent, government agencies have warned the public as to the risks of such products. For instance, in July 2024, FDA sent a letter to compounding advocacy organizations warning that it has received "reports describing patients who experienced adverse events following the administration of compounded . . . tirzepatide."[25] FDA reiterated that "compounded drug products, including compounded . . . tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality."[26] Further, an October 2024 FDA statement warned of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors."[27] Unsurprisingly,

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[24] https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-sterile-products-north-american-custom (FDA notice of voluntary recall).

[25] https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/nursing/fda-safety-alert.pdf (July 16, 2024 FDA letter sent to the Alliance for Pharmacy Compounding and the Outsourcing Facility Association).

[26] *Id.*

[27] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (Oct. 2, 2024 FDA statement on Unapproved GLP-1 Drugs).

poison control centers across the United States have also reported a troubling trend, seeing "a nearly 1,500% increase in calls since 2019 related to overdose or side effects of injectable weight-loss drugs."[28] On January 3, 2025, the South Carolina Attorney General and Illinois Attorney General each issued warnings against compounded tirzepatide drugs. South Carolina Attorney General echoed FDA's warnings that "[u]napproved and compounded products can be risky for consumers because they are not reviewed by FDA for safety, quality, or effectiveness," expressing concern about "unscrupulous sellers [who] are making misleading health claims and promoting unapproved and compounded tirzepatide . . . products in formulations that have never been evaluated by any regulatory agency and may never have been tested in humans at all."[29] Similarly, the Illinois Attorney General warned "about misleading advertising by med spas, wellness centers, online retailers and social media sellers . . . offering compounded drugs" that are not "review[ed] . . . for safety, quality or effectiveness . . . and . . . may pose health risks."

32. Leading health organizations have also expressed concern. Earlier this year, the Obesity Society, Obesity Action Coalition, and Obesity Medicine issued a joint statement regarding compounded GLP-1 medicines, stating, "[u]nfortunately, many of the available

[28] https://poisoncenters.org/track/GLP-1 (Poison Centers report on incretin overdoses).

[29] https://www.scag.gov/about-the-office/news/consumer-alert-attorney-general-alan-wilson-warns-consumers-to-be-cautious-when-purchasing-unapproved-and-compounded-weight-loss-medications/#.

alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[30]

33. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded drugs promoted to aid with weight loss.[31] The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®."[32] As Mark Butler, Australia's Minister for Health, said, "Australians should be able to have faith in the medications they use, including compounded medicines," and the ban "will protect Australians from harm and save lives."[33] Similarly, the South African Health Products Regulatory Authority expressed concerned about compounded tirzepatide products, noting that they "pose[] a public health and safety risk" due to "the unknown nature and safety of ingredients used in compounding."[34]

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30 https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/ (Joint Statement on Compounded GLP-1 Alternatives).

31 https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products (Australia Minister for Health and Aged Care press release).

32 *Id.*

33 *Id.*

34 https://www.sahpra.org.za/news-and-updates/sahpras-position-on-glp1-and-gip-glp1-products-that-are-compounded-substandard-and-falsifiedas/.

III. THRIVE'S FALSE AND DECEPTIVE CLAIMS

34. Thrive is a health and wellness clinic that purports to offer services related to "weight-loss." As part of these services, Thrive promotes (and encourages potential customers to use) its non-FDA-approved, compounded tirzepatide as a claimed weight loss treatment it calls "MEGALean" or "MEGALean Premium" (collectively referred to as "MEGALean"). Thrive claims that MEGALean contain a "proprietary blend of tirzepatide."[35] In particular, Thrive contends that MEGALean is a "pure Tirzepatide product[]" and "[t]he most aggressive medication for weight loss."[36]

35. As set forth in detail below, Thrive has made and continues to make numerous false statements throughout its advertising pertaining to the inherent quality of its MEGALean products, including (A) claims that Thrive's product is "pure" or "100% Pure, " (B) statements that Thrive's MEGALean products are proven to achieve certain therapeutic outcomes, and (C) Thrive's claims regarding the efficacy of its MEGALean products are supported by clinical tests or studies. These false statements go to the inherent nature of Thrive's MEGALean products and deceive consumers as to their nature and quality.

36. A compilation of certain of Thrive's false advertising is discussed below and attached hereto as **Exhibit A**.

A. Thrive's False "100% Pure" and "Pure" Claims

[35] https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/ [https://perma.cc/Y3VM-JLDJ] (capitalization omitted).

[36] https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406.

37. Thrive states on its website that its "Tirzepatide" "Weekly Weight Loss Injection" is "100% Pure Tirzepatide."[37] And as set forth above, on the MEGALean specific page, Thrive states that it "only sells pure Tirzepatide products."[38]

38. Thrive's claims that its MEGALean products are "pure" are false and deceptive because sterility testing of Thrive's product revealed the presence of *Micrococcus luteus*, or *M. Luteus*, bacteria. *M. Luteus* is "a kind of catalase-, oxidase-, and Gram-positive cocci broadly found in natural environments such as soil and water resources."[39] Blood infections with this bacteria can be fatal and have been "reported to possibly cause infections such as hepatic and brain abscess, native valve endocarditis, bacteremia, and septic arthritis in immunosuppressive patients."[40] Because Thrive's product is an injection, any patient who takes MEGALean risks introducing the *M. Luteus* pathogen directly into their bloodstream.

39. Thus, Thrive's products are not "100% Pure Tirzepatide." Nor would any consumers understand a product containing dangerous, indeed potentially life-threatening, bacteria to be "pure" or "100% Pure." The presence of this bacteria is a dangerous public health issue that also renders Thrive's advertising false. Lilly has already alerted the proper authorities of the bacteria found in Thrive's products. But Lilly also brings this suit to put a stop to Thrive's misleading practices and to protect the public from potential harm.

B. Thrive's False Claims of Proven Results

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[37] https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/.

[38] https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406.

[39] https://pmc.ncbi.nlm.nih.gov/articles/PMC8459002/.

[40] *Id.*

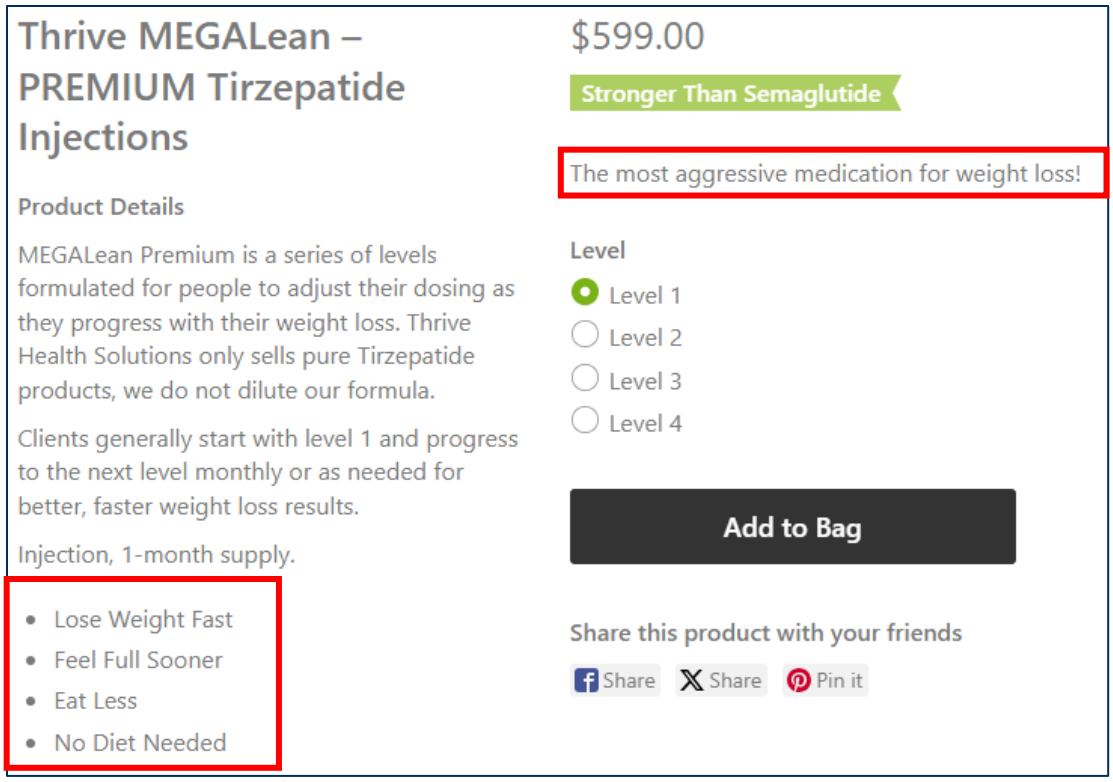
40. Thrive falsely advertises its MEGALean products on its website, located at www.thrivecolorado.com, by making statements that MEGALean is safe and effective for achieving certain therapeutic outcomes. These statements rely on FDA's approval of ***Lilly's*** medicines and clinical trials for those ***Lilly*** medicines. Yet, Lilly's studies and approvals have no bearing on, and cannot substantiate claims about, Thrive's MEGALean products, which by Thrive's own description contain a "proprietary blend" of ingredients that, upon information and belief, are not contained in Lilly's medicines. And, critically, Lilly is not aware of *any* clinical trials on the safety and effectiveness of Thrive's MEGALean drug.

41. As demonstrated in the screenshot below, Thrive's website touts "Tirzepatide" as "the most potent weight loss medication produced so far."[41] "Tirzepatide," however, is ***not*** approved for treatment of weight loss or any other condition; Lilly's MOUNJARO® and ZEPBOUND® medicines ***containing*** tirzepatide are FDA-approved for the indications described above. Rather than offering an FDA-approved medication, Thrive sells unapproved, untested, and unstudied compounded drugs.

[41] https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/.

42. Thrive also describes MEGALean as "[t]he ***most aggressive*** medication for weight loss," promising to allow patients to "Lose Weight Fast" with "No Diet Needed."[42]

[42] https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406.



43. In fact, Thrive's website used to advertise MEGALean as FDA-approved, claiming that "Thrive . . . sells pure ***FDA-approved*** Tirzepatide products" and that its "Tirzepatide weekly weight loss injection is the most potent ***FDA-approved*** weight loss medication ever produced."

44. Thrive makes these and other false claims on its social media. For example, in the Instagram post shown below, Thrive stated "***when the FDA approved them***, they specified that patients taking ***meds like Semaglutide and Tirzepatide*** should also" maintain a healthy lifestyle.[43] Additionally, in the Facebook post shown below, Thrive stated "GLP-1 medications are FDA-approved to help with weight loss" in a caption for an image displaying the offerings:

[43] *But see* https://www.instagram.com/p/DAZJqfbygG8/?igsh=bjkzaWJwMHVyZzlw (removing the reference to FDA approval).

"Tirzepatide Injections," "GLP-1 Injections," and "Semaglutide Injections."[44] However, "tirzepatide" has not been approved by FDA. Rather, FDA has approved just two *medicines* containing tirzepatide: Lilly's MOUNJARO® and ZEPBOUND®.

[44] This post has since been deleted.

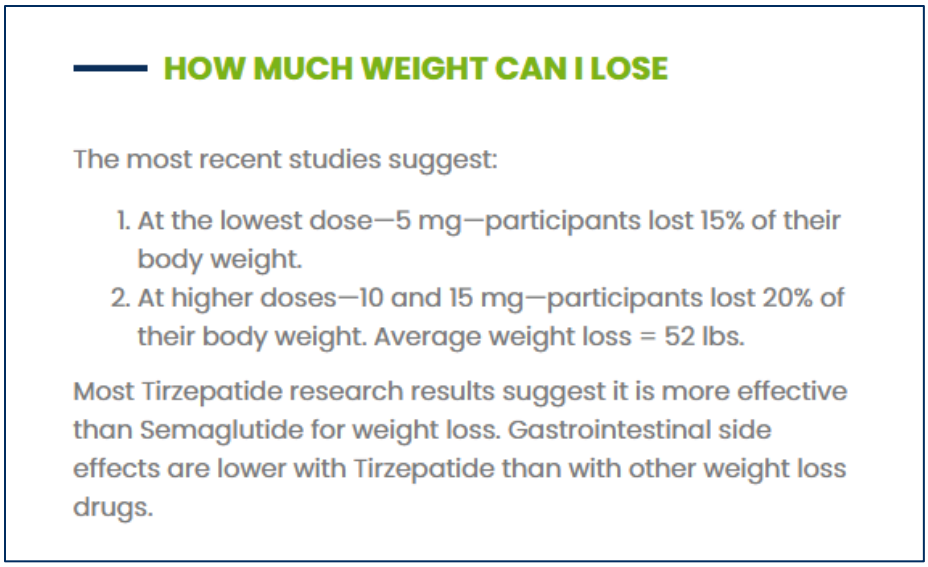
45. Thrive also falsely advertises that its tirzepatide offerings are "safe" and "effective." For example, in the Instagram post shown below, Thrive advertised that its GLP-1 treatments, including "Both Semaglutide and Tirzepatide," help to "shed weight safely and effectively."[45] Upon information and belief, "tirzepatide" itself has not been proven safe or effective for weight loss. Only Lilly's MOUNJARO® and ZEPBOUND® medicines ***containing*** tirzepatide have been found to be safe and effective for treating adults with type 2 diabetes

[45] https://www.instagram.com/p/DBRNX0fR7Dn/?igsh=NnJwNGJpbGRsaWMz.

(MOUNJARO®) and overweight or obese adults with a weight-related condition (ZEPBOUND®).

C. Thrive's False "Clinical Trial" Claims

46. On the "Tirzepatide" subpage of Thrive's website, Thrive also includes the "How Much Weight Can I Lose" infographic shown below:

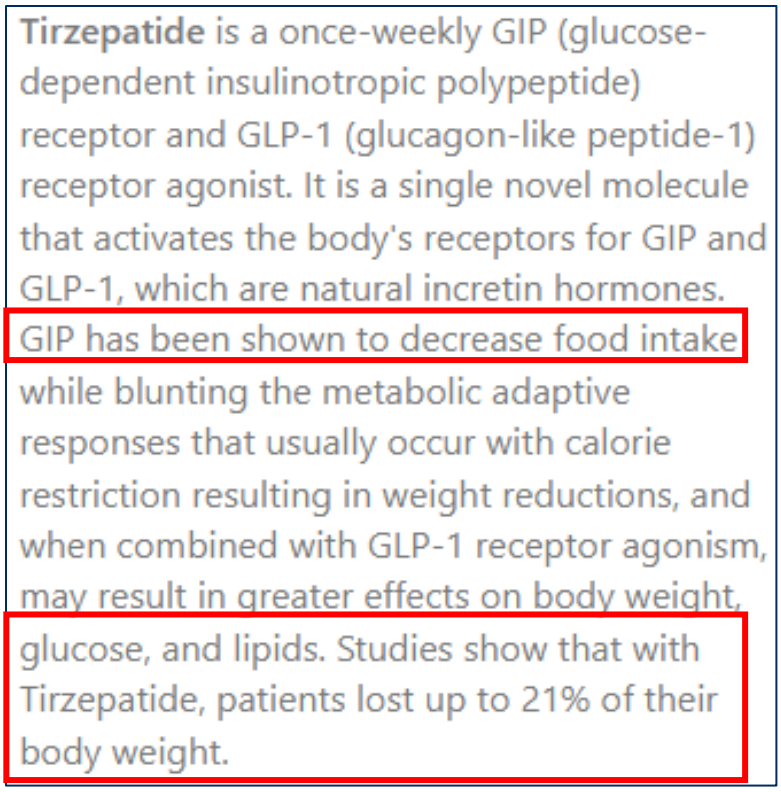


47. This infographic claims that participants of "recent studies" lost between 15–20% of their body weight while using "Tirzepatide"; that the product is "more effective than Semaglutide"; and that "[g]astrointestinal side effects" are lower than with other options.[46]

48. Similarly, on the "Thrive MEGALean" product subpage of Thrive's website, Thrive falsely claims that "GIP has been shown to decrease food intake" and that "[s]tudies show that with Tirzepatide, patients lost up to 21% of their body weight."[47]

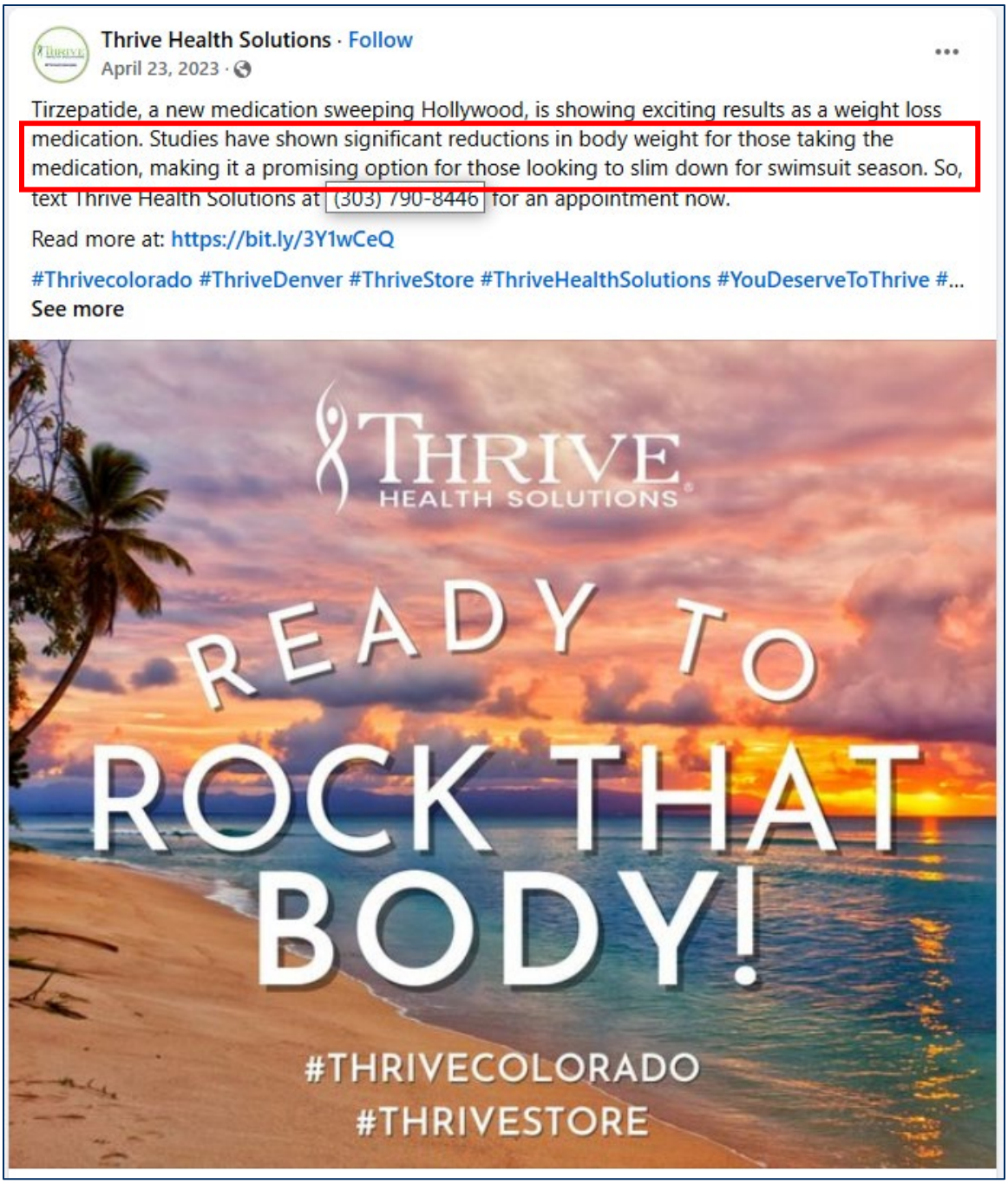
[46] https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/.

[47] https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406.



49. Thrive makes similar false claims on its social media pages. For example, in the Facebook post shown below, Thrive claimed that tirzepatide was "showing exciting results as a weight loss medication" and that "[s]tudies have shown significant reductions in body weight for those taking the medication."[48]

[48] https://www.facebook.com/share/p/1C1o9HFy1S/?mibextid=wwXlfr.



50. The advertising described above communicates to consumers that Thrive's MEGALean products have actually been clinically tested and shown to facilitate weight loss, yet, on information and belief, no such clinical trials have been conducted.

51. Instead, Thrive relies on studies conducted on ***Lilly's*** medicines when making statements that its MEGALean products are effective for achieving certain therapeutic outcomes. These clinical trials have no bearing on, and cannot substantiate, claims about Thrive's MEGALean products, which purport to contain a "proprietary blend" of ingredients that, upon information and belief, are not included in Lilly's medicines and that, on information and belief, are sold without having undergone ***any*** testing for safety or effectiveness in achieving any of the therapeutic outcomes claimed. Notably, neither MOUNJARO® nor ZEPBOUND® is indicated for cosmetic weight loss.

52. Thrive's references to "studies" are clear establishment claims (*i.e.* "tests prove" types of claims). Such claims must be supported by the kind of testing described in the advertisement. Where the advertiser lacks the testing discussed in its advertising, its claims are false. Here, Thrive's advertising expressly and repeatedly references "studies" and "research" in discussing the safety and efficacy of its MEGALean products. Thus, Thrive must have clinical studies proving that its product—*i.e.*, its proprietary blend of tirzepatide—is safe and effective for weight loss. Upon information and belief, Thrive does not have any clinical data assessing the safety or effectiveness of tirzepatide, as the only studies undertaken on a medication containing tirzepatide are those conducted regarding Lilly's MOUNJARO® and ZEPBOUND® medications. Lilly's clinical studies are irrelevant to the safety and efficacy of Thrive's MEGALean products.

* * *

53. In short, throughout its advertising Thrive makes a series of false and deceptive claims that state that its MEGALean products—a "propriety blend of tirzepatide"—are pure and clinically tested and backed by specific scientific research to provide safe and effective weight loss

benefits. Thrive even advertised on social media that its product was FDA-approved. These statements—individually and collectively—communicate to prospective purchasers that Thrive's untested and unapproved drugs are proven safe and effective for the treatment of that person's type 2 diabetes or obesity. Quite the contrary: no regulator—let alone FDA—has evaluated the safety or effectiveness of Thrive's MEGALean products. Lilly is unaware of any data supporting Thrive's representation that its MEGALean products are safe and effective. In fact, the opposite is true: an evaluation of a sample of Thrive's MEGALean revealed the presence of dangerous bacteria.

54. Thrive's false and deceptive statements are intended—and likely—to cause confusion, to cause mistake, or to deceive consumers as to the nature and quality of Thrive's MEGALean products. Further, these statements present a significant patient safety risk, as these statements have the tendency to draw the public away from using safe, effective, FDA-approved medicines and encourage the use of untested, unapproved, and unsafe compounded drugs.

IV. HARM TO THE PEOPLE OF COLORADO AND LILLY

55. Thrive's false, deceptive, and reckless promotion and sale of its products has harmed Lilly and the people of Colorado and will continue to do so if left unchecked.

56. First, Thrive's false statements lure consumers away from obtaining safe and effective treatment with MOUNJARO® and ZEPBOUND® on the false statement that Thrive's MEGALean products are safe and effective in helping people treat diabetes and address chronic weight management. This not only has injured Lilly, but more importantly risks severe harm to consumers—at best financially, but far worse injury is possible, as is demonstrated by the recent

evaluation of a sample of Thrive's MEGALean product, which revealed the presence of a *Micrococcus luteus* contamination.

57. Second, Thrive's misrepresentations cause irreparable damage to Lilly's brand and customer goodwill by promising results that consumers will not obtain from Thrive's MEGALean products. Consumers may also be physically harmed due to the presence of harmful bacteria in Thrive's MEGALean products. When consumers fail to achieve desired results from, or become ill due to, Thrive's MEGALean products, they will associate tirzepatide with being ineffective in general. Therefore, consumers will undoubtedly draw negative inferences as to Lilly's medicines as well.

FIRST CAUSE OF ACTION
False Advertising and Promotion
in Violation of 15 U.S.C. § 1125(a)(1)(B)

58. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

59. Thrive's commercial advertising claims described herein are false and deceptive in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

60. Thrive has knowingly and willfully made materially false and deceptive statements in its commercial advertisements for its MEGALean products (including its website and social media). These statements regarding alleged clinical studies purportedly supporting the safety or effectiveness of Thrive's MEGALean products, as well as the so-called purity of those products, have influenced and are likely to continue to influence consumers' purchasing decisions—specifically, decisions to purchase Thrive's MEGALean products instead of Lilly's FDA-approved medicines. As a result, Thrive is steering patients with serious diseases like diabetes and obesity

away from obtaining safe, effective, available, and FDA-approved treatments. Thrive's unlawful conduct is putting health, safety, and lives at risk.

61. Thrive has caused its false statements to enter interstate trade or commerce.

62. As a direct and proximate result of Thrive's false and deceptive campaign, Lilly is suffering immediate and continuing irreparable injury for which there is no adequate remedy at law.

63. As a direct and proximate result of Thrive's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the loss of goodwill.

64. This is an exceptional case under 15 U.S.C. § 1117.

65. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Thrive's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

SECOND CAUSE OF ACTION
Deceptive Trade Practices
in Violation of C.R.S. §§ 6-1-101 *et seq*.

66. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

67. Thrive's above-described acts constitute deceptive trade practices in violation C.R.S. §§ 6-1-101 *et seq.*

68. Among other things, C.R.S. § 6-1-105 defines actions that constitute a "deceptive trade practice" as including, but not limited to, when a person, in the course of the person's business, vocation, or occupation, does the following:

(a) Either knowingly or recklessly passes off goods, services, or property as those of another;

(b) Either knowingly or recklessly makes a false representation as to the source, sponsorship, approval, or certification of goods, services, or property;

(c) Either knowingly or recklessly makes a false representation as to affiliation, connection, or association with or certification by another;

* * *

(e) Either knowingly or recklessly makes a false representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods, food, services, or property or a false representation as to the sponsorship, approval, status, affiliation, or connection of a person therewith;

* * *

(g) Represents that goods, food, services, or property are of a particular standard, quality, or grade, or that goods are of a particular style or model, if he knows or should know that they are of another;

* * *

(i) Advertises goods, services, or property with intent not to sell them as advertised;

* * *

(u) Fails to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction.

69. As set forth herein, Thrive's actions fit within the scope of C.R.S. § 6-1-105.

70. Evidence that Thrive has engaged in these deceptive trade practices is prima facie evidence of Thrive's intent to injure competitors and to destroy or substantially lessen competition under C.R.S. § 6-1-105(2).

71. Thrive has knowingly and willfully made materially false and deceptive statements in its commercial advertising for its MEGALean products (including its website and social media accounts). These representations amount to false assurances of the safety, quality, purity, and effectiveness of Thrive's MEGALean products. Thrive's false and deceptive misrepresentations and omissions are material because they involve information that would be important to consumers, and therefore, likely their use of or conduct regarding Thrive's MEGALean products.

72. Because Thrive conducts sales online, a significant number of Thrive's consumers will encounter Thrive's services via its website, on which Thrive engages in false advertising.

73. Because Thrive's misrepresentations are advertised directly to the public as potential or actual consumers, a significant public impact is presumed.

74. As a direct and proximate result of the actions of Thrive alleged above, Lilly has been injured and damaged and will continue to be injured and damaged, making Thrive liable to Lilly under C.R.S. § 6-1-113.

75. Under C.R.S. § 6-1-113, Thrive is liable to Lilly for damages, including treble damages, as a result of Thrive's bad faith conduct. In addition, Lilly is entitled to attorneys' fees and costs.

76. Thrive's conduct, unless enjoined by the Court, will further impair the value of the Lilly's name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

77. Members of the public are also likely to suffer injury from Thrive's above-described acts by purchasing a drug that they believe to be clinically studied, safe and

effective, like Lilly's MOUNJARO® and ZEPBOUND®, not an unapproved, untested, and unstudied compounded drug.

78. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief.

JURY DEMAND

Lilly hereby demands a jury trial for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in its favor on its claim for relief set forth above and award it relief including, but not limited to, the following:

1. An Order declaring that Thrive:

   a. Engaged in false and deceptive advertising and promotion, in violation of 15 U.S.C. § 1125(a)(1)(B);

   b. Engaged in deceptive trade practices in violation C.R.S. §§ 6-1-101 *et seq*; and

   c. That each of the above acts was willful and knowing.

2. An injunction preliminarily and then permanently enjoining and restraining Thrive and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, from:

   a. Falsely stating that Thrive's MEGALean products are FDA-approved, have been the subject of clinical studies, achieve certain therapeutic outcomes, or are pure; and

   b. Engaging in any deceptive or unfair acts.

3. An Order requiring Thrive and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, to engage in corrective advertising by informing consumers that:

a. Thrive's MEGALean products are not and have never been approved by FDA;

b. Thrive's MEGALean products have never been studied in clinical trials;

c. Thrive's MEGALean products have never been demonstrated to be safe or effective; and

d. Thrive's MEGALean products are not "100% Pure."

4. An Order directing Thrive to file with this Court and serve on Lilly's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which it has complied with the Court's injunction.

5. An Order requiring Thrive to account for and pay to Lilly any and all profits arising from the foregoing acts of false advertising.

6. An Order requiring Thrive to pay Lilly compensatory damages in an amount as yet undetermined caused by the false advertising and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117 and other applicable laws.

7. An Order requiring Thrive to pay Lilly all types of monetary remedies available under Colorado's Deceptive Trade Practices Act in amounts as yet undetermined caused by the foregoing deceptive trade practices.

8. An Order for pre-judgment and post-judgment interest on all damages.

9. An Order requiring Thrive to pay Lilly's costs and attorney fees in this action pursuant to 15 U.S.C. § 1117, Colorado state law, and any other applicable provision of law.

10. Other relief as the Court may deem appropriate.

Dated: January 13, 2025

Respectfully submitted,

/s/ Daniel N. Guisbond

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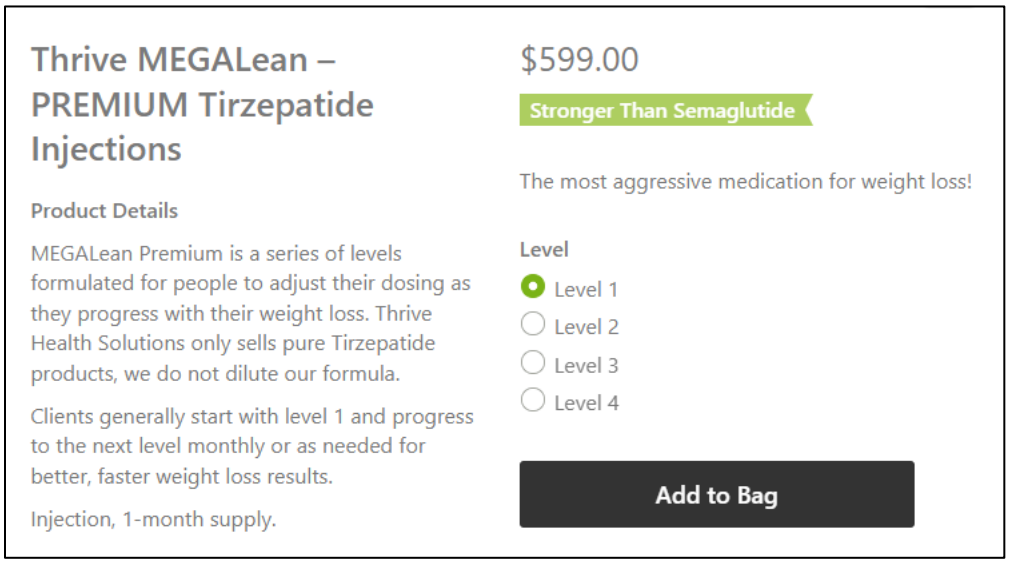
Attorneys for Plaintiff
ELI LILLY AND COMPANY

Exhibit A

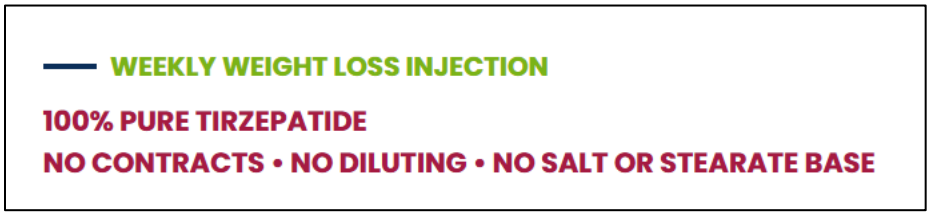

WEEKLY WEIGHT LOSS INJECTION
100% PURE TIRZEPATIDE
NO CONTRACTS • NO DILUTING • NO SALT OR STEARATE BASE
Tirzepatide weekly weight loss injection is the most potent weight loss medication produced so far with an average weight loss of more than 23% of starting weight. It's the first and only dual GIP/GLP-1 receptor agonist hormone that controls both insulin and glucagon secretion. In addition, the GIP hormone controls lipids and fat deposits in the body. The two hormones in the once-a-week Tirzepatide injection work together as a single molecule. Acting in the brain, stomach, pancreas, and bowel. Tirzepatide controls appetite, fullness, and metabolism.
In addition, like Semaglutide, it delays gastric emptying, producing fullness for many hours. Tirzepatide is prescribed "off label" for weight loss, similar to Semaglutide. More significant weight loss and glucose control and fewer side effects are found with Tirzepatide than with Semaglutide because it consists of 2 active hormones acting together.
MEGALEAN
TIRZEPATIDE
Thrive Tirzepatide:
Thrive currently offers Tirzepatide as an injectable.
Tirzepatide Injection: An option where you can adjust dosage as needed, this option is comprised of only Tirzepatide.
Starting at $699
BUY NOW


THRIVE HEALTH SOLUTIONS
Tirzepatide Options
MEGALEAN
TIRZEPATIDE
Thrive MEGALean Tirzepatide Injectable
Proprietary Blend of Tirzepatide

Source: https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/; https://perma.cc/Y3VM-JLDJ



Source: https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406



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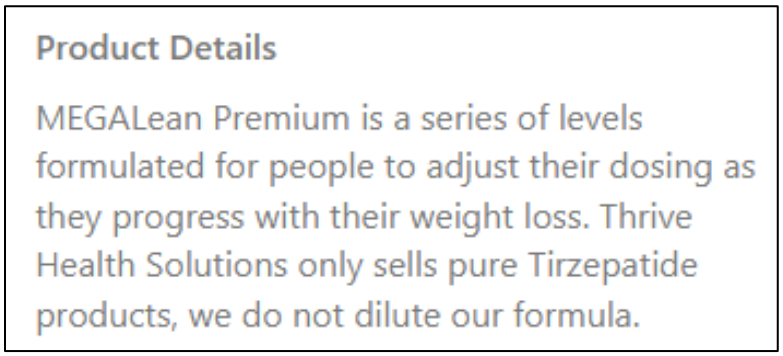


Source: https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406

Tirzepatide weekly weight loss injection is the most potent weight loss medication produced so far with an average weight loss of more than 23% of starting weight. It's the first and only dual GIP/GLP-1 receptor agonist hormone that controls both insulin and glucagon secretion. In addition, the GIP hormone controls lipids and fat deposits in the body. The two hormones in the once-a-week Tirzepatide injection work together as a single molecule. Acting in the brain, stomach, pancreas, and bowel. Tirzepatide controls appetite, fullness, and metabolism.

Source: https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/

$599.00

Stronger Than Semaglutide

The most aggressive medication for weight loss!

- Lose Weight Fast
- Feel Full Sooner
- Eat Less
- No Diet Needed

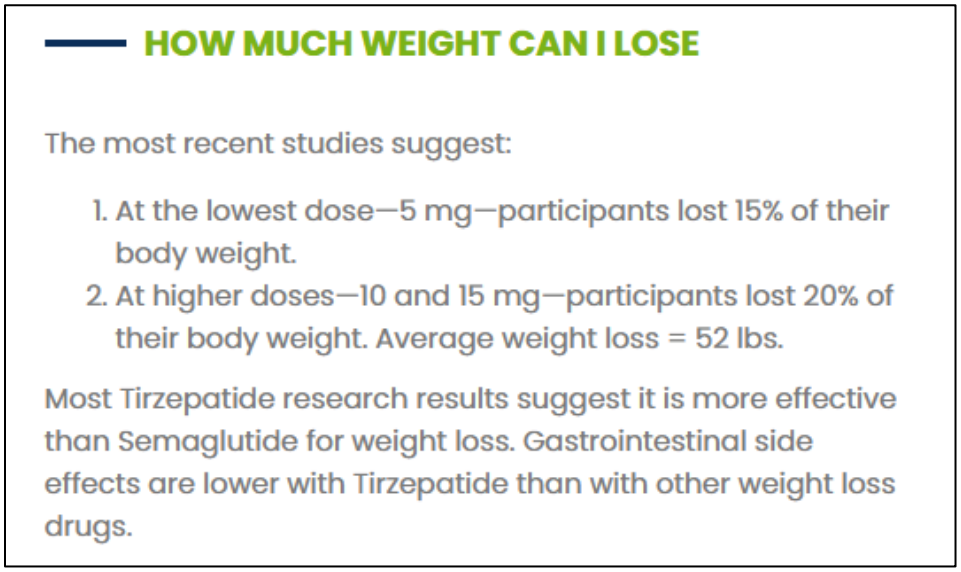
Source: https://thrivecolorado.com/store/Thrive-Tirzepatide-Injections-p509533406

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 13, 2025, I electronically filed the foregoing **COMPLAINT FOR FALSE ADVERTISING AND DECEPTIVE TRADE PRACTICES** with the Clerk of the Court using the CM/ECF system.

/s/ Daniel N. Guisbond
Daniel N. Guisbond
Attorney for Plaintiff
ELI LILLY AND COMPANY

Source: https://www.instagram.com/p/DBRNX0fR7Dn/?igsh=bmltYmN3ZzB0b2U%3D



Source: https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/

Tirzepatide is a once-weekly GIP (glucose-dependent insulinotropic polypeptide) receptor and GLP-1 (glucagon-like peptide-1) receptor agonist. It is a single novel molecule that activates the body's receptors for GIP and GLP-1, which are natural incretin hormones. GIP has been shown to decrease food intake while blunting the metabolic adaptive responses that usually occur with calorie restriction resulting in weight reductions, and when combined with GLP-1 receptor agonism, may result in greater effects on body weight, glucose, and lipids. Studies show that with Tirzepatide, patients lost up to 21% of their body weight.

Source: https://thrivecolorado.com/store/Thrive-MEGALean-PREMIUM-Tirzepatide-Injections-p509533406

Source: https://www.facebook.com/thrivehealthsolutionsco